

## REMARKS

Favorable reconsideration of this application is respectfully requested in view of the following remarks.

By way of this Amendment, new Claims 34-42 are presented for consideration.

Appreciation is expressed to Examiner Marcetich for the indicated allowability of Claims 3, 4 and 7-13. Thus, the only claims currently at issue are Claims 15, 16, 26-30 and 34-42. Claims 20 and 34 are the only independent claims.

The only issue raised in the Official Action involves the rejection of independent Claim 12, and the associated dependent claims, under 35 U.S.C. § 112, second paragraph. To respond to the concern raised about the filter being connected to the second tube/loop or the connected bag set, Claim 20 is amended to adopt the helpful suggestion made by the Examiner. That is, Claim 20 defines the blood treatment circuit in terms of a product-by-process. New Claim 34 is also a product-by-process claim.

The Official Action correctly notes that the claimed manner in which the blood treatment circuit here is assembled by aseptically connecting the filter unit to the connected bag is distinguishable over the prior art. The Examiner comments though that a product-by-process claim must distinguish over the prior art in terms of the structure which results from the method. That is, an unobvious difference must exist between the claimed product and the prior art product. Here, such an unobvious difference exists.

In one respect, it is apparent that the way in which the blood circuit here is assembled -- aseptically by cutting the tubes and then connecting together the cut ends of the cut tubes -- results in a region along each tube where the two tubes are

connected. That is, a connection joint exists at the region where the cut ends of the tube are connected.

On the other hand, in prior art blood circuits that do not use an assembly process like that used here, the tube extending between the primary bag and the filter unit is devoid of any connection joints. Similarly, the tube extending between the filter unit and the secondary bags is devoid of any connection joints.

Thus, in the blood treatment circuit here, the structure of the tube extending between the primary bag and the filter unit is structurally different -- the tube includes a connection joint at the place where the second tube and the first/third tube are joined. In at least that respect, there is certainly a structural difference that results from the process used to assemble the blood treatment circuit at issue here.

In addition, a structural difference would exist with respect to the filter unit itself. As discussed in the present application, the need for subjecting the filter to the same type of sterilization as the remaining parts of the blood treatment circuit can deteriorate the filter medium of the filter. This same deteriorated condition of the filter medium of the filter unit in the blood treatment circuit at issue here does not occur because it is possible to filter unit separate from the other components before the filter unit is connected.

Thus, from a structural standpoint, the blood treatment circuit assembled according to the method recited in Claims 20 and 34 results in structurally different filter unit because the filter medium is not deteriorated.

In light of the foregoing, it is respectfully submitted that the product-by-process claims at issue here as set forth in independent Claims 20 and 34 results in a product that differs from the blood treatment circuit produced according to known

methods. It is thus respectfully submitted that independent Claims 20 and 34, and the associated dependent claims, are also allowable.

To further emphasize the structural differences resulting from the different manner of assembly, Claims 39 and 40 are added and recite that the connected bag set is a moist heat sterilized connected bag set, while the filter unit is not a moist heat sterilized filter unit. Claims 41 and 42 are also added and recite that the connected bag set is a moist heat sterilized connected bag set, and the filter unit is a gas sterilized filter unit or a radiation sterilized filter unit. These claims recite structural differences. Indeed, a moist heat sterilized connected bag set is structurally different from a connected set that is not so sterilized. It is thus respectfully submitted that these dependent claims further differentiate the product-by-process claims at issue here.

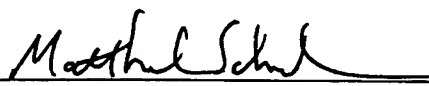
Early and favorable action concerning this application is respectfully requested.

Should any questions arise concerning this application or should the Examiner believe a telephone conference with the undersigned would be helpful in resolving any remaining issues pertaining to this application the undersigned respectfully requests that he be contacted at the number indicated below.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

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By:   
Matthew L. Schneider  
Registration No. 32814

P.O. Box 1404  
Alexandria, VA 22313-1404  
703 836 6620